STATE MEDICAID DUR BOARD MEETING

THURSDAY, July 8, 2010
7:00 a.m. to 8:30 a.m.
Cannon Health Building
Room 114

MINUTES

Board Members Present:

Mark Balk, PharmD
Tony Dalpiaz, PharmD.
Brad Hare, M.D.
Wilhelm Lehmann, M.D.
Cris Cowley, M.D.
Kathy Goodfellow, R.Ph.
Dominic DeRose, R.Ph.
Peter Knudson, DDS
Joseph Miner, M.D.
Joseph Yau, M.D.

Board Members Excused:

Neal Catalano, R.Ph.
Bradley Pace, PA-C

Dept. of Health/Div. of Health Care Financing Staff Present:

Jennifer Zeleny, CPhT, MPH
Tim Morley, R.Ph.
Merelynn Berrett, R.N.
Amber Kelly, R.N.
Lisa Hulbert, R.Ph.
Richard Sorenson, R.N.
Marisha Kissel, R.N.

Other Individuals Present:

Pat Wiseman, Medimmune
Lori Howarth, Bayer
Brett Brewer, EMD Serono
Sabrina Aery, BMS
Ann Marie Licos, Medimmunue
Cap Ferry, LEC
Susan Stone, Allergan

Meeting conducted by: Wilhelm Lehmann, M.D.

1 Review and Approval of Minutes: The minutes were reviewed and corrected. The motion to approve the corrected minutes was made by Dominic DeRose. Mark Balk seconded the motion. The motion passed with unanimous votes by Dr. Miner, Dr. Dalpiaz, Dr. Yau, Dr. Balk, Dr. Hare, Dr. Knudson, and Kathy Goodfellow.

2 Housekeeping: Dominic DeRose was thanked for ten years of service on the DUR Board and was presented with a plaque.

3 P&T Committee Report: Lisa Hulbert addressed the Board. The last P&T Meeting was in May, and the Committee looked at Nicotine Replacement Therapy and Human Growth Hormone. The next meeting is scheduled for July 15.

4 Toradol quantity limit: Lisa Hulbert addressed the Board, and reviewed materials prepared

by Utah Medicaid in support of covering it for a maximum of five days and twenty doses per month. Utilization data was provided to demonstrate that excessive utilization is a problem with Utah Medicaid clients.

Dr. Hare stated that as a non-selective cox inhibitor, there is nothing special about the drug itself other than its parenteral availability. He has never been a big fan of the oral dosage form, because the available oral doses are smaller than the parenteral doses, and there are nasty GI side effects. He wanted to eliminate the oral dosage form totally. There are some situations where injectable is appropriate for short-term use.

Lisa stated that in the injections there was only one claim for 60 vials that would have been halted with a quantity limit. The abuse is mainly in the oral dosage form. Because ketorolac is a rebatable drug, Medicaid cannot get rid of it altogether, but can put a very strict PA on it to reduce the use.

Dr. Hare was not sure that there was ever a legitimate use for oral ketorolac due to the side effects. Dr. Lehmann proposed a failure of at least three other oral NSAIDS prior to trying ketorolac and then giving a PA for a very small quantity. Dr. Yau added that it should only be used as a continuation of IV or IM therapy.

Jennifer Zeleny summarized the recommendations for the PA:

- Available only as a continuation of IV/IM therapy.
- Documented failure of at least three other oral NSAIDS.
- Limited to a total of five days of use.

Mark Balk added a minimum age of 18 years old.

Dr. Yau moved to accept the criteria as proposed. Mark Balk seconded the motion.

The Board asked if any action was being taken on injectable. Lisa stated that is up to the Board, because only one client in almost six months of claims history would have had their claim denied. The Board felt that a quantity limit for a total of 20 doses in five days was appropriate. The motion passed with unanimous votes by Dr. Cowley, Dr. Miner, Dr. Dalpiaz, Dr. Yau, Dr. Balk, Dr. Hare, Dr. Knudson, and Kathy Goodfellow.

Dominic DeRose moved to place quantity limits on the IV/IM dosage form of ketorolac. Dr. Hare seconded the motion. The motion passed with unanimous votes by Dr. Cowley, Dr. Miner, Dr. Dalpiaz, Dr. Yau, Dr. Balk, Dr. Hare, Dr. Knudson, and Kathy Goodfellow.

5 Istodax: Lisa Hulbert addressed the Board and presented materials prepared by Utah Medicaid in support of placing Istodax on PA. It is indicated for the treatment of cutaneous T-cell Lymphoma. It is not a first-line drug. Proposed PA criteria were presented to the Board.

Dr. Yau clarified whether or not this will be paid through the pharmacy or physician's

billing. Lisa stated that Medicaid will reimburse it through the physician's office only. Medicaid can't handle having payment available through both the medical and the pharmacy side, because the system can't prevent double billing. The billing system is old, and can't edit medical claims against pharmacy claims and vice versa. Because this drug requires medical supervision while being infused, Medicaid feels that paying the HCPCS code is the most appropriate method of reimbursement.

Mark Balk moved to accept the criteria as written. Tony Dalpiaz seconded the motion. The motion passed with unanimous votes by Dr. Cowley, Dr. Miner, Dr. Dalpiaz, Dr. Yau, Dr. Balk, Dr. Hare, Dr. Knudson, and Kathy Goodfellow.

6 Tysabri: Lisa Hulbert addressed the Board. She presented materials prepared by Utah Medicaid in support of a PA. It is not indicated for first-line use and has some significant safety concerns that caused it to be pulled from the market for a brief time in 2005. Proposed PA criteria were presented.

Mark Balk suggested for Crohn's Disease that concomitant use with immunomodulators and Anti-TNF agents were ruled out as part of that disease state's PA.

Dr. Miner suggested removing corticosteroids and budesonide from the inadequate response. It is consistent with the package insert, and not allow concomitant use with Tysabri. Lisa stated that the failure of corticosteroids is not a requirement, but corticosteroids were listed as one of many agents that could be failed.

The DUR Board felt it was reasonable to get rid of the budesonide and corticosteroids altogether from the list of drugs that could be failed. Additionally, the DUR Board wanted to not allow concomitant use of any immunomodulators, not just anti-TNF's. Of the list of conventional therapies, only aminosalycilates and antibiotics were acceptable to be taken with Tysabri.

The Board also suggested that the last bullet point for Crohn's disease read, "Documented failure or intolerance" to the anti-TNF agent, to be consistent with the criteria for MS.

7 Ampyra: Lisa Hulbert addressed the Board. This product is indicated to improve walking in patients with MS. It is brought to the DUR Board due to safety. There is an increased risk of seizures with the drugs, and there is a dose dependant increase in risk. Lisa presented materials prepared by Utah Medicaid outlining all of the safety concerns and proposed PA criteria.

Dr. Hare moved to approve the PA criteria as proposed. Tony Dalpiaz seconded the motion. The motion passed with unanimous votes by Dr. Cowley, Dr. Miner, Dr. Dalpiaz, Dr. Yau, Dr. Balk, Dr. Hare, Dr. Knudson, and Kathy Goodfellow.

The next DUR Board meeting was scheduled for Thursday September 9, 2010.

The DUR Board Prior Approval Subcommittee to considered 2 petitions this month. 1 was

approved.

Minutes prepared by Jennifer Zeleny